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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09 674,330	12/20/2000	Tasuku Honjo	Q61536	5233

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2100 Pennsylvania Avenue NW
Washington, DC 20037

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/18/2002

157

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,330

Applicant(s)

HONJO ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> | 6) <input type="checkbox"/> Other |

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a first Office action on the merits (Paper No. 14, mailed on January 25, 2002), Applicants filed an amendment and response received on July 25, 2002 (Paper No. 18). Said amendment included a substitute specification that has been entered; said amendment cancelled Claim 9, amended Claims 1-6, 8, and 10-13, and added new Claim 14. Thus, Claims 1-8 and 10-14 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the International Application No. PCT/JP99/02283 filed on April 28, 1999 and Japanese application 10-119731 filed on April 28, 1998 as requested in the declaration.

Information Disclosure Statement

3. The information disclosure statement filed on July 25, 2002 (Paper No. 17) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Drawings

4. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

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Withdrawn - Objections to the Specification

5. Previous objection to the specification for the numerous spelling and typographical errors is withdrawn by virtue of Applicants' amendment in the form of the substitute specification.

6. Previous objection to the specification for a confusing description of the sequence listing sequences is withdrawn by virtue of Applicants' addition to the specification, Table I on page 33, that clearly and plainly describes the sequences. Since the sequences were previously disclosed and their description previously being obvious, this table does not add new matter to the specification. Also, the identification of "A55b" (a new descriptor) and the exon discussion on page 35 clearly and plainly describes the second A55 isoform and also does not add new matter since the sequences were previously disclosed and their description previously being obvious.

7. Previous objection to the specification for the confusing BrdU incorporation assay is withdrawn by virtue of Applicants' adding a description of the assay into the specification; this description is not considered new matter because it is well known in the art.

8. Previous objection to the Abstract for its form and content is withdrawn by virtue of Applicants' amendment to the Abstract.

9. Previous objection to the Title is withdrawn by virtue of Applicants' amendment.

Withdrawn - Objections to the Claims

10. Previous objection to Claims 6-8 under 37 C.F.R. § 1.75(c) as being in improper form because of multiple dependent claim 6 is withdrawn by virtue of Applicants' amendment.

11. Previous objection to Claim 8 under 37 C.F.R. § 1.75(c) as being in improper form because of multiple dependent claim 8 is withdrawn by virtue of Applicants' amendment.

12. Previous objection to Claim 10 for containing non-elected subject matter is withdrawn by virtue of Applicants' amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

13. Previous rejection of Claims 1-8 and 10-13 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "that comprising" is withdrawn by virtue of Applicants' amendment.

14. Previous rejection of Claims 1, 3, 5-8, and 10-13 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "homologue" is withdrawn by virtue of Applicants' amendment.

15. Previous rejection of Claims 2, 8, and 10-13 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "consists (comprising)" is withdrawn by virtue of Applicants' amendment.

16. Previous rejection of Claims 6-8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "carrying" is withdrawn by virtue of Applicants' amendment.

17. Previous rejection of Claim 13 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to specify method steps is withdrawn by virtue of Applicants' amendment.

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18. Previous rejection of Claims 4-5 under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment limiting the scope of the claims to exact cDNA structures whose functions are inherent in the structures. Rejection of Claims 1, 3, 6-8, and 10-13 is maintained below because the functional language added to Claim 1 is unclear (see below).

19. Previous rejection of Claims 1-8 and 10-13 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn. Applicants' arguments and additional data have been fully considered. While the Examiner is not convinced of the inhibitory activity on proliferation of the A55 polypeptide as described in the specification and defended in Applicants' arguments, other art (Nakamura *et al.* see IDS #17) identifies this polypeptide and how to use it as a vascular ligand for integrin receptors. This other art is not contrary to Applicants' assertion and offers other means of using the claimed invention.

20. Previous rejection of Claims 10-12 under 35 U.S.C. § 112, first paragraph, enablement, for the "pharmaceutical compositions" is withdrawn as noted above, in general, for the A55 polypeptide.

Maintained - Claim Rejections - 35 U.S.C. § 112

21. Previous rejection of Claims 1, 3, 6-8, and 10-13 under 35 U.S.C. 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants' argue that the limitation of the varied structure combined with the functional requirement, "having the same function", meets all the limitations of the written

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description requirement. This is not the case because the functional language is unclear (see below). Functional language is crucial, in combination with a variable structure, to describe a genus of claimed products as previously noted in the written description rejection. Moreover, Claim 3 does not limit the cDNA functionally in the second half of the claim (after the "or").

Withdrawn - Claim Rejections - 35 U.S.C. § 101

22. Previous rejection of Claims 1-8 and 10-13 under 35 U.S.C. § 101 is withdrawn as noted above, in general, for the enablement of the A55 polypeptide.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

23. Previous rejection of Claims 3-5 under 35 U.S.C. § 102(b) as being anticipated by Lee *et al.* is withdrawn by virtue of Applicants' amendment. Lee *et al.* teach an mRNA encoding a fragment of Applicants' A55 polypeptide that is highly similar in sequence; however, the amended claims require the similarity over the full length of the sequence, thus obviating the rejection.

24. Previous rejection of Claims 1, 3-8 and 10-13 under 35 U.S.C. § 102(e) as being anticipated by Bandman *et al.* is withdrawn by virtue of Applicants' amendment. Bandman *et al.* teach a polypeptide that is 94% identical to SEQ ID NOs:4 and 9; this does not anticipate the amended claims requiring at least 95% identity to the disclosed sequences.

25. Previous rejection of Claims 3-5 under 35 U.S.C. § 102(a) as being anticipated by Marra *et al.* is withdrawn. Marra *et al.* teach an mRNA encoding a fragment of Applicants' A55

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polypeptide that is highly similar in sequence; however, the amended claims require the similarity over the full length of the sequence, thus obviating the rejection.

Withdrawn - Claim Rejections - 35 U.S.C. § 103

26. Previous rejection of Claims 1 and 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Lee *et al.* in view of Bork *et al.* is withdrawn for the reasons cited above concerning Lee *et al.*, which is no longer considered prior art against the claims.

27. Previous rejection of Claims 1 6-8 and 10-12 under 35 U.S.C. § 103(a) as being unpatentable over Marra *et al.* in view of Bork *et al.* is withdrawn for the reasons cited above concerning Marra *et al.*, which is no longer considered prior art against the claims.

NEW OBJECTIONS/REJECTIONS

Objections to the Specification

28. The amendment filed July 25, 2002 (Paper No. 18) is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: in Claim 13, culturing two sets of cells and comparing them. Applicants cite support for this amendment from page 26 of the substitute specification. While page 26 describes screening compounds, that is agonists/antagonists, no controls are described for such an assay.

Applicant is required to cancel the new matter in the reply to this Office Action.

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Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 1-8 and 10-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "having the same function" is unclear. Presumably, the word "same" means having the same function as the A55 or A55b polypeptide, although this is not clear. Moreover, what function is that? The function required of the polypeptides claimed is wholly unclear.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

30. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, new matter, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new matter is described above as being in Claim 13.

Summary of Pending Issues

31. The following is a summary of the issues pending in the instant application:
- a) The amendment filed July 25, 2002 (Paper No. 18) stands objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure.
 - b) Claims 1-8 and 10-14 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "having the same function".
 - c) Claims 1, 3, 6-8, and 10-13 stand rejected under 35 U.S.C. 112, first paragraph, written description.
 - d) Claim 13 stands rejected under 35 U.S.C. § 112, first paragraph, new matter.

Conclusion

32. Claims 1-8 and 10-14 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R.

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§ 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be "KMK", is located in the center-right of the page.

KMK
October 17, 2002